

CORPORATE INTEGRITY AGREEMENT

Northeast Alabama Kidney Clinic

This Corporate Integrity Agreement ("the Agreement") is entered into between Northeast Alabama Kidney Clinic, an Alabama corporation ("NEAKC"), Renal Care Group, Inc., a Delaware corporation ("Renal Care Group"), and the Office of Inspector General of the United States Department of Health and Human Services ("OIG-HHS"). Pursuant to this Agreement, NEAKC and Renal Care Group agree to undertake the compliance obligations outlined below.

I. Preamble

NEAKC is a wholly-owned subsidiary of Renal Care Group. NEAKC owns and currently operates a twenty-five station End Stage Renal Dialysis ("ESRD") facility in Anniston, Alabama, and a ten station ESRD facility in Talladega, Alabama. NEAKC provides no other service aside from outpatient ESRD therapy.

OIG-HHS has entered into the certain Settlement Agreement and Release of even date herewith among the United States, NEAKC, and Renal Care Group.

NEAKC agrees to implement a Corporate Integrity Program as described herein to prevent fraud, abuse, and false billing to Medicare, Medicaid and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)), by NEAKC and by its subsidiaries, employees, independent contractors and third parties who are directly involved in or responsible for the delivery of outpatient renal dialysis services and who are involved in or directly or indirectly responsible for the submission of claims for outpatient renal dialysis services to Medicare, Medicaid and other Federal health care programs. The Corporate Integrity Program described herein shall be maintained so that NEAKC and each of its directors, officers, employees and contractors maintain the business integrity required of a participant in Federal health care programs, and that NEAKC is in compliance with all laws and regulations applicable to such programs and with the terms of the Agreement set out below.

On October 29, 1998, Renal Care Group provided to the OIG-HHS a copy of Renal Care Group's compliance manual entitled *Statement of Policies of Renal Care Group, Inc. and Its Affiliated Organizations Regarding Compliance with Laws, Business Ethics, and Standards of Conduct for Employees*, August 1998 (the "Renal Care Group

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Compliance Manual”), attached hereto as “Attachment A.” The Renal Care Group Compliance Manual describes the Renal Care Group compliance program (the “Renal Care Group Compliance Program”) and is intended to cover NEAKC’s own compliance efforts. Accordingly, the NEAKC Corporate Integrity Program described herein is intended to complement, but not supplant, NEAKC’s compliance efforts under the Renal Care Group Compliance Program. Also, NEAKC and Renal Care Group agree to continue to apply the Renal Care Group Compliance Program (as described in Attachment A) to NEAKC for the duration of this Agreement, and agree to notify OIG-HHS of any material changes in the Renal Care Group Compliance Program within thirty (30) days of any such change.

II. Corporate Integrity Policies and Code of Standards

The period of future compliance obligations under this Agreement shall be three (3) years and sixty (60) days from the date of execution of this Agreement. The date of execution of this Agreement shall be deemed to be the date of the final signature for this Agreement. All reports and notifications required under this Agreement shall be sent to:

Civil Recoveries Branch -- Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building Room 5527
330 Independence Avenue, S.W.
Washington, D.C. 20201
(202) 619-2078 Phone
(202) 205-0604 Fax

All OIG-HHS correspondence and notifications sent to NEAKC shall be sent to:

Compliance Officer & General Counsel
Renal Care Group, Inc.
2100 West End Avenue
Suite 800
Nashville, Tennessee 37203
(615) 345-5500 Phone
(615) 345-5503 Fax

NEAKC and Renal Care Group agree to implement the following measures within the time periods specified below and maintain the measures until at least three years and sixty (60) days after the date of execution of this Agreement, unless otherwise specified in this Agreement:

A. Corporate Compliance Officer & Corporate Compliance Committee

Within thirty (30) days of the execution of this Agreement and for at least the remaining term of this Agreement, Renal Care Group's Compliance Officer (*see*, Attachment A, page 3) will assume and retain primary responsibility for NEAKC's compliance operations and reporting requirements under this Agreement. In addition, for the term of this Agreement, Renal Care Group's Compliance Officer shall be a member of Renal Care Group's management and an officer of Renal Care Group and shall have the authority to report directly to Renal Care Group's Board of Directors.

Within thirty (30) days of the execution of this Agreement and for at least the remaining term of this Agreement, Renal Care Group's Compliance Committee (*see*, Attachment A, page 3) will assume and retain oversight responsibility for NEAKC's Corporate Integrity Program. The members of Renal Care Group's Compliance Committee shall at least include Renal Care Group's Compliance Officer and one corporate officer of NEAKC.

B. Corporate Compliance Policy and Procedures

Within ninety (90) days of the execution of this Agreement and for at least the remaining term of this Agreement, NEAKC shall implement written policies and procedures regarding its commitment to ensure compliance with all laws and regulations related to the delivery of outpatient renal dialysis services, including the requirement that all services be accurately documented by the individual providing the service and accurately represented in any claims for payment, *i.e.*, claims for payment should be submitted only for services actually provided. NEAKC's policies and procedures shall be adopted by its Board of Directors and distributed to all employees and independent contractors involved with Federal health care programs within thirty (30) days of the commencement of the employee's or independent contractor's involvement with Federal health care programs. NEAKC may use the Renal Care Group Compliance Manual for the articulation, implementation and dissemination of these written policies and procedures (*see*, Attachment A, page 24), but must employ additional materials if the

Renal Care Group Compliance Manual does not contain all of NEAKC's obligations under this Agreement.

NEAKC's policies and procedures shall include, but will not be limited to the requirement that Renal Care Group's Compliance Officer perform on-site inspections of locations where NEAKC provides care to beneficiaries of Federal health care programs, and periodic sampling (at least quarterly) of documents, including but not limited to employee or independent contractor time sheets, progress notes, service logs, and billing sheets to verify compliance with applicable Medicare, Medicaid and other Federal statutes, regulations and guidelines. This on-site inspection and periodic sampling obligation are independent from the on-site investigations described in the Renal Care Group Compliance Manual (*see*, Attachment A, page 8).

NEAKC shall post in a prominent place accessible to each appropriate employee a notice detailing its own commitment to comply with all applicable Medicare, Medicaid and other Federal laws and regulations in the conduct of its business.

C. Billing and Contracting Procedures

1. Annual Review

NEAKC shall contract with an independent professional organization, such as an accounting firm, law firm or health care consultant to review on an annual basis NEAKC's dealings with Medicare, Medicaid and other Federal health care programs, and especially its practices relating to internal processes and controls so that services provided are accurately recorded and billed. Such annual review shall comply with the Annual Review Protocol that is attached hereto as Attachment B and incorporated herein by this reference. The review shall assess whether NEAKC's internal processes and controls are adequate to determine whether NEAKC is submitting accurate claims for services billed to Medicare, Medicaid and other Federal health care programs, and whether an effective procedure is in place to correct inaccurate billings. The review shall also assess whether NEAKC's policies, procedures and operations comply with the terms of this Agreement.

2. Mandatory Disclosure of Probable Violations of Law

If, during the term of this Agreement, the independent reviewer or the Renal Care Group Compliance Committee and/or Compliance Officer discover(s) credible evidence of misconduct from any source and, after reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law concerning NEAKC's practices related to Federal health care programs, then Renal Care Group's Compliance Officer will promptly report (but in no case more than sixty (60) days after discovering the evidence) such probable violation of law to OIG-HHS. The Compliance Officer's report to OIG-HHS will include (a) the annual review's findings, if any, concerning any such probable violation, (b) NEAKC's actions to correct such probable violation, and (c) any further steps it plans to take to address such probable violation and prevent it from recurring in the future. A corrective action plan to remedy the probable violation of law should be in place within sixty (60) days. NEAKC will make the corrective action plan available to the OIG-HHS upon request.

3. Mandatory Disclosure of Deficiencies

If, during the term of this Agreement, the independent reviewer or Renal Care Group's Compliance Officer and/or Compliance Committee discover(s) any material deficiency related to NEAKC's dealings with Medicare, Medicaid, or any other Federal health care program, then within sixty (60) days of discovering the material deficiency Renal Care Group's Compliance Officer will report the material deficiency to the relevant Medicaid agency, Medicare contractor, carrier, fiscal intermediary, or other relevant payor, and NEAKC will repay any overpayment resulting from the material deficiency.

The notice to the Medicaid agency, Medicare contractor, carrier, intermediary, or other relevant payor should state that the repayment is being made pursuant to the terms of this Corporate Integrity Agreement and should include: (i) the methodology by which the overpayment was determined; (ii) information that identifies the claims that led to the overpayment; (iii) the amount of the overpayment; and (iv) the date of the

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check and the check number (or electronic transaction number) on which the overpayment was repaid.

Contemporaneous with the notification to the payor as provided above, Renal Care Group's Compliance Officer shall notify OIG-HHS of the following: (i) all of the information provided to the Medicaid agency, Medicare contractor, carrier, intermediary, or other relevant payor in returning the overpayment; (ii) the name and address of the Medicaid agency, Medicare contractor, carrier, intermediary, or other relevant payor to whom the overpayment was sent; (iii) the Compliance Officer's and/or Compliance Committee's findings concerning the deficiency; (iv) NEAKC's action to correct the deficiency; and (v) any further steps NEAKC plans to take to address such deficiency and prevent it from recurring.

For purposes of this Agreement, a "material deficiency" shall mean anything that has a significant, adverse financial impact upon Medicare, Medicaid or any other Federal health care program, which may be the result of an isolated event or a series of occurrences, and which is a probable violation of the reimbursement statutes and regulations of Medicare, Medicaid or other Federal health care programs, such as the regulations and written directives issued by the Health Care Financing Administration ("HCFA") and/or its agents, or any other agency/agents charged with administering the Federal health care program implicated.

If NEAKC or Renal Care Group's Compliance Officer or Compliance Committee learns of any overpayment to NEAKC (regardless of whether it results from a "material deficiency" and regardless of its size), NEAKC shall promptly (but in no event later than sixty (60) days after discovering the overpayment) bring such overpayment to the appropriate payer's attention, make appropriate refunds, and take appropriate steps to prevent the occurrence in the future.

For purposes of this Agreement, an "overpayment" shall mean the amount of money the provider has received in excess of the amount due and payable under the Medicare, Medicaid or other Federal health care program's statutes and regulations.

D. Training and Education

Within ninety (90) days of the execution date of this Agreement, NEAKC or Renal Care Group shall institute and maintain training and education programs designed to make each officer, director, and employee of NEAKC aware of all applicable health care laws, including Medicare, Medicaid and other Federal health care program laws, regulations, and standards of business conduct that such individual is expected to follow and the consequences both to the individual and NEAKC that will ensue from any violation of such requirements. Each officer, director, employee and new hire of NEAKC shall receive at least one hour of training regarding the NEAKC Corporate Integrity Agreement. A copy of all training materials shall be made available upon request of the OIG-HHS. The training and education program may include, but not be limited to, the education program described in the Renal Care Group Compliance Manual (*see*, Attachment A, page 7).

E. Confidential Disclosure Program

For at least the term of this Agreement, Renal Care Group shall make available to NEAKC employees the confidential disclosure program described in the Renal Care Group Compliance Manual (*see*, Attachment A, page 4). The confidential disclosure program shall enable NEAKC employees to disclose to Renal Care Group's Compliance Officer or a designee not in that employee's direct chain of command any practices or billing procedures deemed by the employee to be inappropriate. Renal Care Group and/or NEAKC shall, as part of the Corporate Integrity Program, require the internal review of any such disclosure and shall require that follow-up is conducted within ten (10) days of the disclosure. The Compliance Officer shall maintain a confidential disclosure log, which shall include a record of each allegation received, status of the investigation of the allegation, and any corrective action taken in response to the investigation. The Compliance Officer shall maintain all documentation related to information in the log and make such documents available for inspection by OIG-HHS upon request.

F. Dealing with Excluded or Convicted Persons or Entities

Definition. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has

been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

Screening Requirements. NEAKC shall use appropriate efforts not to hire or engage as contractors any Ineligible Person. To fulfill such obligation, NEAKC shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.arnet.gov/epl>) and the HHS/OIG Cumulative Sanction Report (available through the Internet at <http://www.dhhs.gov/progorg/oig>) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

Review and Removal Requirement. Within ninety (90) days of the effective date of this Agreement, NEAKC will review its list of current employees and contractors against the Exclusion Lists. Thereafter, NEAKC will review the list once semi-annually. If NEAKC has notice that an employee, agent, or physician has become an Ineligible Person, NEAKC will remove such person from responsibility for, or involvement with, NEAKC's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

Pending Charges and Proposed Exclusions. If NEAKC has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with NEAKC, within 10 days of receiving such notice NEAKC will remove such individual from responsibility for, or involvement with, NEAKC's business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

G. Interim and Annual Reports

Within one-hundred and twenty (120) days following the execution of this Agreement, NEAKC shall do the following: (1) provide OIG-HHS with a report of the steps taken to satisfy section II.B., *Corporate Compliance Policies and Procedures*, above; and, (2) notify OIG-HHS of the identities of the members of the Renal Care Group Compliance Committee.

On or before the sixtieth (60th) day beyond the first, second, and third anniversary dates of the execution of this Agreement, NEAKC shall provide OIG-HHS with a report ("Annual Report") relating to the following items:

- (1) A summary of NEAKC's knowledge of any ongoing investigation or legal proceeding conducted or brought by any governmental entity involving an allegation that NEAKC may have committed a crime or may have engaged in fraudulent activities related to billing for services provided under the Medicare, Medicaid or other Federal health care programs. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding.
- (2) A description of the findings and recommendations made during the reviews and audits conducted pursuant to this Agreement relating to the year of the Annual Report, and a description of the corrective steps taken.
- (3) A status report of the communications received from the confidential disclosure program pertaining to NEAKC, established pursuant to Paragraph E of this section, including but not limited to a description of the disclosures received and a copy of the confidential disclosure log described in Paragraph E, and the results of any investigations performed as a result of any disclosures.
- (4) A report of the aggregate amount of any overpayments to NEAKC that have been returned to the Medicare, Medicaid and other Federal health care programs, that were discovered as a direct or indirect result of the Corporate Integrity Program established pursuant to this Agreement. The report should include a detailed description of how the overpayments were

calculated, as well as a copy of all of the information provided to payors regarding the overpayment(s). The second and third Annual Reports shall compare the frequency and amount of NEAKC's overpayments to the frequency and amount of its overpayments in the prior year(s) covered by this Agreement.

- (5) A description of all personnel actions (other than hiring) taken by NEAKC as a result of the requirements in Paragraph F of this section.
- (6) In the first Annual Report, the document or documents that comprise NEAKC's corporate compliance policies established under Paragraph B of this section as adopted by NEAKC's Board of Directors and implemented by the Renal Care Group Compliance Committee. For subsequent years, NEAKC shall note in the report any amendments or revisions to the corporate compliance policy documents made during the year of the Annual Report.
- (7) A description of the training and education program implemented pursuant to Paragraph D of this section and the activities engaged in during the year of the Annual Report in furtherance of the training and education program.
- (8) Any changes to the members of NEAKC's officers, directors or Renal Care Group Compliance Committee members since the previous Annual Report.
- (9) A resolution (or its equivalent) from NEAKC's Board of Directors certifying that they have reviewed the Annual Reports and agree with the statements made therein.

III. OIG-HHS Inspection, Audit and Review Rights

In addition to any other right that OIG-HHS may have by statute, regulation, contract or pursuant to this Agreement, OIG-HHS or its duly authorized representative(s) may examine any of NEAKC and/or Renal Care Group's non-privileged books, records, and other company documents and supporting materials for the purpose of verifying and evaluating: (a) NEAKC and/or Renal Care Group's compliance with the terms of this Agreement; (b) NEAKC's business conduct in its dealing with the United States Government, or any agencies or agents thereof; and (c) NEAKC's compliance with the

requirements of Medicare, Medicaid and other Federal health care programs. The documentation described above shall, upon reasonable prior notice to NEAKC and/or Renal Care Group, be made available by NEAKC and/or Renal Care Group at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG-HHS or its authorized representative(s) may interview any NEAKC employee and/or Renal Care Group employee with involvement in NEAKC's Corporate Integrity Program who consents to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG-HHS; employees may elect to be interviewed with or without a representative of NEAKC or Renal Care Group present, but each employee has the right to have counsel present at the interview.

IV. Document and Record Retention

NEAKC shall maintain for inspection documents and records relating to Medicare, Medicaid or other Federal reimbursement for a period of six (6) years following the execution of this Agreement, or for whatever other period of time required by law or policy, whichever is longer.

V. Breach and Default Provisions

NEAKC and Renal Care Group's compliance with the terms and conditions of this Agreement shall constitute an element of NEAKC's present responsibility with regard to direct or indirect participation in Federal health care programs. Full and timely compliance by NEAKC and Renal Care Group shall be expected throughout the duration of this Agreement with respect to all of the obligations herein.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, NEAKC and OIG-HHS hereby agree that failure to comply with certain obligations set forth in this Agreement may lead, in the discretion of OIG-HHS, to the imposition of specific monetary penalties (hereinafter referred to as "stipulated penalties") in accordance with the following provisions.

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1. A stipulated penalty of \$1,000 for each day that NEAKC fails to comply with any of the following, which stipulated penalty shall begin to accrue on the date the obligation becomes due:
 - a. failure to submit the complete Annual Report to OIG-HHS when due;
 - b. failure to submit to OIG-HHS those items that are required to be submitted within one-hundred and twenty (120) days of the date of execution of this Agreement, pursuant to section II.G., above;
2. A stipulated penalty of \$1,000 for each day NEAKC fails to comply by having fully in force during the term of this Agreement any of the following, which stipulated penalty shall begin to accrue on the date the failure to comply begins:
 - a. a Compliance Officer as required under section II.A. of this Agreement;
 - b. a Corporate Compliance Committee as required under section II.A. of this Agreement;
 - c. written policies and procedures as required under section II.B. of this Agreement;
 - d. the training and education program required under section II.D. of this Agreement;
 - e. the confidential disclosure program required under section II.E. of this Agreement.
3. A stipulated penalty of \$1,000 for each day NEAKC or Renal Care Group fails to grant reasonable access to the information or documentation necessary to exercise the OIG-HHS's inspection, audit and review rights set forth in section III of this Agreement, which stipulated penalty shall begin to accrue on the date NEAKC or Renal Care Group fails to grant reasonable access.

4. A stipulated penalty of \$1,000 (which shall begin to accrue on the date the failure to comply begins) for each day NEAKC:
 - a. hires or enters into a contract with an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this stipulated penalty shall not be owed for any time period during which NEAKC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section II.F) as to the status of the person);
 - b. employs or contracts with an Ineligible Person and that person: (i) has responsibility for or involvement with NEAKC's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this stipulated penalty shall not be owed for any time period during which NEAKC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section II.F) as to the status of the person); or
 - c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, NEAKC's business operations related to the Federal health care programs (this stipulated penalty shall not be demanded for any time period before ten (10) days after NEAKC received notice of the relevant matter or after the resolution of the matter).
5. A stipulated penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG-HHS provides notice to NEAKC or Renal Care

Group of the failure to comply) for each day NEAKC or Renal Care Group fails to comply fully and adequately with any obligation of this Agreement. In its notice to NEAKC or Renal Care Group, OIG-HHS shall state the specific grounds for its determination that NEAKC or Renal Care Group has failed to comply fully and adequately with the obligation(s) at issue. With respect to the stipulated penalty provision described in this section V.A.5 only, OIG-HHS shall not seek a stipulated penalty if NEAKC or Renal Care Group demonstrates to OIG-HHS' satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that: (i) NEAKC or Renal Care Group has begun to take action to cure the failure to comply, (ii) NEAKC or Renal Care Group is pursuing such action with due diligence, and (iii) NEAKC or Renal Care Group has provided to OIG-HHS a reasonable timetable for curing the failure to comply.

B. Payment of Stipulated Penalties

Upon finding that NEAKC or Renal Care Group has failed to comply with any of the above-enumerated obligations, OIG-HHS may choose to demand payment of the stipulated penalties above. To effectuate the demand, OIG-HHS shall notify NEAKC or Renal Care Group of: (i) the failure to comply; and (ii) OIG-HHS's exercise of its contractual right to demand payment of the stipulated penalties payable under this Agreement (this notification is hereinafter referred to as the "Demand Letter").

Within twenty (20) days of receipt of the Demand Letter, NEAKC or Renal Care Group shall respond by either: (i) curing the breach to the OIG-HHS's satisfaction and paying the applicable stipulated penalties; or (ii) sending in writing to the OIG-HHS a request for a hearing before an HHS administrative law judge to dispute the OIG-HHS's determination of noncompliance, pursuant to the agreed upon provisions set forth in Paragraph D of this section, below. Failure to respond to the Demand Letter shall be considered a material breach of this Agreement and shall be grounds for exclusion under Paragraph C of this section, below.

If NEAKC or Renal Care Group submits a timely written request to OIG-HHS for an extension of the relevant time period to perform any act or file any notification or report under this Agreement, OIG-HHS agrees that Stipulated Penalties shall not begin to accrue until two (2) business days following NEAKC or Renal Care

Group's receipt of OIG-HHS's written denial of such a request. A "timely written request" is defined as a request in writing received by OIG-HHS at least five (5) business days prior to the date by which any act is due to be performed or notification or report is due to be filed.

Payment of the stipulated penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OCIG at the address set forth in section II of this Agreement.

C. Material Breach and Exclusion

If NEAKC or Renal Care Group engages in conduct that OIG-HHS considers to be a material breach of this Agreement, OIG-HHS may seek exclusion of NEAKC from participation in the Medicare, Medicaid and any other Federal health care programs (as defined in 42 U.S.C. §1320a-7b(f)).

Upon making its determination, OIG-HHS shall notify NEAKC of the alleged material breach by certified mail and of its intent to exclude as a result thereof (this letter shall be referred to hereinafter as the "Notice of Material Breach and Intent to Exclude"). NEAKC shall have thirty-five (35) days from the date of the letter to:

- (1) demonstrate to the OIG-HHS's satisfaction that NEAKC or Renal Care Group is in full compliance with this Agreement;
- (2) cure the alleged material breach; or
- (3) demonstrate to the OIG-HHS's satisfaction that the alleged material breach cannot be cured within the thirty-five (35) day period, but that NEAKC or Renal Care Group has begun to take action to cure the material breach and that such action shall be pursued with due diligence. NEAKC shall, at this time, submit a timetable for curing the material breach for the OIG-HHS's approval.

If, at the conclusion of the thirty-five day period (or other specific period as subsequently agreed to by the parties), NEAKC fails to meet the requirements of provisions 1, 2 or 3 above, OIG-HHS may exclude NEAKC from participation in

the Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. §1320a-7b(f)). OIG-HHS shall notify NEAKC in writing of its determination to exclude (this letter shall be referred to hereinafter as the "Exclusion Letter").

The exclusion shall take effect thirty (30) days from the date of the Exclusion Letter unless NEAKC exercises its contractual right to seek review of the OIG-HHS's exclusion determination by requesting a hearing before an administrative law judge as provided in Paragraph D ("Review Process") of this section, below. In the event such a hearing is requested, the exclusion shall not be effective until the issuance of an administrative law judge's decision supporting the OIG-HHS's exclusion determination, as provided below in Paragraph D of this section. The exclusion shall have national effect and will also apply to all other Federal procurement and non-procurement programs.

A material breach of this Agreement means: (i) a failure by NEAKC or Renal Care Group to meet an obligation under this Agreement where the failure has a significant adverse impact on the integrity of Medicare, Medicaid, or any other Federal health care program (for example, a failure to report a material billing deficiency, take corrective action and pay the appropriate refunds, as provided in Paragraph C(3) of section II of this Agreement); or (ii) repeated or flagrant violations of the obligations under this Agreement.

D. Review Process

Review Rights. Upon the OIG-HHS's delivery to NEAKC or Renal Care Group of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligations of this Agreement, NEAKC or Renal Care Group shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the stipulated penalties or exclusion sought pursuant to this Agreement. Specifically, the OIG-HHS's determination to demand payment of stipulated penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21.

Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within thirty (30) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this Agreement shall be (a) whether NEAKC or Renal Care Group was in full and timely compliance with the obligations of this Agreement for which the OIG-HHS demands payment; and (b) the period of noncompliance. If the ALJ finds for the OIG-HHS with regard to a finding of a breach of this Agreement and orders NEAKC or Renal Care Group to pay stipulated penalties, such stipulated penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that NEAKC or Renal Care Group may request review of the ALJ decision by the DAB.

Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be (a) whether NEAKC or Renal Care Group was in material breach of this Agreement; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the 35 day period, but that (i) NEAKC or Renal Care Group has begun to take action to cure the material breach, (ii) NEAKC or Renal Care Group is pursuing such action with due diligence, and (iii) NEAKC or Renal Care Group has provided to OIG-HHS a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG-HHS. NEAKC or Renal Care Group's election of its contractual right to appeal to the DAB shall not abrogate the OIG-HHS's authority to exclude NEAKC upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG-HHS and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that NEAKC or Renal Care Group may request review of the ALJ decision by the DAB.

VI. Additional Compliance Audit or Review

In addition to the obligations assumed by NEAKC and Renal Care Group under the Agreement and as described above, if OIG-HHS reasonably determines and communicates to NEAKC or Renal Care Group that it is necessary to conduct an independent audit or review to determine whether or to the extent to which NEAKC or Renal Care Group is complying with its obligation under this Agreement, NEAKC agrees to pay for the reasonable cost of any such audit or review.

VII. Privileges

Nothing in this Agreement, or any communication or report made pursuant to this Agreement, shall constitute or be construed as any waiver by any party of its attorney-client, work product or other applicable privileges.

VIII. Confidentiality

Subject to HHS's Freedom of Information Regulations, set forth in 45 C.F.R. part 5, the OIG-HHS shall make a reasonable effort to notify NEAKC or Renal Care Group prior to any release by the OIG-HHS of information submitted by NEAKC or Renal Care Group pursuant to its obligations under this Agreement and identified upon submission as trade secrets or privileged or confidential commercial or financial information within the meaning of the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4), and HHS's Freedom of Information Regulations, 45 C.F.R. § 5.65. NEAKC and Renal Care Group will refrain from identifying any information as trade secrets or privileged or confidential commercial or financial information unless the information meets the criteria for exemption from disclosure under FOIA and HHS's Freedom of Information Regulations. Nothing in this Agreement shall be construed to prohibit OIG-HHS from providing information to any other department or agency of the United States Government or any State charged with enforcing the laws against health care fraud if the information relates to matters within the department's or agency's jurisdiction, provided that any such entity receiving such information shall be advised by OIG-HHS of the confidentiality provisions of this Agreement.

IX. Effective and Binding Agreement

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, NEAKC, Renal Care Group and the OIG agree as follows:

1. this Agreement shall be binding on the successors, assigns and transferees of NEAKC and Renal Care Group, including, without limitation, any entity to whom Renal Care Group would seek to transfer the operations currently undertaken by NEAKC, provided that (A) in the case of a disposition by Renal Care Group of the NEAKC entity to an unrelated third party after which NEAKC would remain obligated hereunder and the third party would be bound by this Agreement and Renal Care Group would have no control over the operations of NEAKC, then Renal Care Group shall have no further obligations hereunder; and (B) in the case of a disposition of the assets and operations of NEAKC to an unrelated third party that enters into a new agreement with OIG-HHS to assume both NEAKC and Renal Care Group's obligations hereunder, then neither NEAKC nor Renal Care Group shall have any further obligations hereunder;
2. this Agreement shall become final and binding upon signing by each respective party hereto;
3. any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement; and
4. the undersigned NEAKC signatories represent and warrant that they are authorized to execute this Agreement. The undersigned United States signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

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IN WITNESS WHEREOF, the parties hereto affix their signatures

FOR NORTHEAST ALABAMA KIDNEY CLINIC, INC.:

09/28/99

Date

Sam A. Brooks

Sam A. Brooks

President

c/o Renal Care Group, Inc.

2100 West End Avenue

Suite 800

Nashville, Tennessee 37203

Tel. 615/345-5500; Fax 615/345-5503

FOR RENAL CARE GROUP, INC:

09/28/99

Date

Sam A. Brooks

Sam A. Brooks

President

Renal Care Group, Inc.

2100 West End Avenue

Suite 800

Nashville, Tennessee 37203

Tel. 615/345-5500; Fax 615/345-5503

Approved as to form:

9-27-99

Date

Frank G. Smith, III

Frank G. Smith, III

Attorney for Northeast Alabama Kidney Clinic

Alston & Bird LLP

One Atlantic Center

1201 West Peachtree Street


Atlanta, Georgia 30309-3424

Tel. 404/881-7000; Fax 404/881-7777

Corporate Integrity Agreement with OIG-HHS

FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

10/6/99
Date



Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
Department of Health and Human Services